Biotech Daily

Wednesday March 30, 2016

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: ANTEO UP 6%, USCOM DOWN 8%**

*** OPTHEA EXPECTS OPT-302 FOR WET AMD SAFETY RESULTS IN APRIL**

*** MMJ PREPARES LUCKY LAKE FOR 10-FOLD MARIJUANA PRODUCTION**

*** IDT SUB-CONTRACTS CANADA'S WELLSPRING FOR MANUFACTURE**

*** BRIAN DOVEY REPLACES REVA CHAIRMAN ROBERT STOCKMAN**

MARKET REPORT

The Australian stock market was up 0.12 percent on Wednesday March 30, 2016 with the ASX200 up 5.8 points to 5,010.3 points.

Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and two were untraded. All three Big Caps were up.

Anteo was the best, up 0.3 cents or 6.1 percent to 5.2 cents with 461,466 shares traded, followed by Psivida up 21 cents or six percent to $3.71 with 1,500 shares traded.

Sirtex climbed 4.6 percent; Atcor, Bionomics, IDT and Oncosil were up more than three percent; Starpharma and Universal Biosensors rose more than two percent; Clinuvel, Cochlear, Compumedics, CSL and Polynovo were up more than one percent; with Pro Medicus and Resmed up by less than one percent.

Uscom led the falls, down 1.5 cents or 7.9 percent to 17.5 cents with 76,688 shares traded, followed by Antisense down 0.3 cents or seven percent to four cents with 207,306 shares traded.

Cellmid and Tissue Therapies lost more than five percent; Admedus, Benitec and Prana fell four percent or more; Orthocell was down 3.95 percent; Actinogen, Opthea and Prima shed more than two percent; Biotron and Impedimed were down more than one percent; with Medical Developments, Mesoblast, Nanosonics and Viralytics down by less than one percent.

OPTHEA (FORMERLY CIRCADIAN TECHNOLOGIES)

Opthea says it has completed enrolment in its 20-patient, phase I, dose-escalation trial of OPT-302 for wet age-related macular degeneration (AMD).

Opthea said that primary safety data from the four cohorts of five patients each was expected in April with clinical activity expected by October 2016.

The company said that patients in the US Food and Drug Administration approved trial would continue monthly dosing for three months.

Opthea said the trial at 14 US sites was the "first-in-human, open-label, sequential dose-escalation study … to evaluate the safety and clinical activity of intra-vitreal injections of OPT-302 either in combination with standard of care ranibizumab (Lucentis) or alone as monotherapy for patients with wet AMD".

The company said that three cohorts received 0.5mg Lucentis with 0.3mg, 1.0mg or 2.0mg of OPT- 302, respectively and the fourth had 2.0mg OPT-302 as a monotherapy.

Opthea said that OPT-302 at 0.3mg and 1.0mg with Lucentis had been "well tolerated with a promising safety profile in both treatment naïve and previously treated patients".

The company said it expected to complete the 28-day safety assessment at the 2.0mg highest dose level in April, which was a primary objective of the trial.

Opthea said that the complete data analysis would include secondary endpoint measurements of clinical activity, such as changes from baseline in visual acuity and wet AMD lesions using optical coherence tomography and fluorescein angiography imaging, with the results to be presented at a clinical ophthalmology conference later in the year.

Opthea chief executive officer Dr Megan Baldwin said that completed enrolment was "an important milestone for Opthea".

Opthea fell one cent or 2.3 percent to 42.5 cents.

MMJ PHYTOTECH

MMJ says that it has begun the process of obtaining regulatory approval for a second medical marijuana production facility at Lucky Lake, Saskatchewan.

In February, MMJ said that its10,000 square feet (929 square metres) Duncan, British Columbia facility had completed its pre-licence inspection for Health Canada with a response expected in mid-March (BD: Feb 5, 16, 2016).

Today, MMJ chief executive officer Andreas Gedeon told Biotech Daily that he could not influence the regulatory process but said that Supreme Pharmaceuticals had its final inspection in December 2015 and recently received its licence.

MMJ said in a media release that subsidiary United Greeneries owned the 62,000 square feet (5,760sqm) facility on about 18 acres (7.3ha) and when completed would increase its production capacity of dried cannabis flowers by up to 12,000kg a year, with the land and infrastructure capable of accommodating large greenhouse structures.

The company said the Lucky Lake application was at the enhanced screening stage, where the proposed health, safety and security measures at the facility would be examined.

MMJ said that once approved under the Marijuana for Medical Purposes Regulations, the Lucky Lake facility would be integrated with the Duncan facility, expanding production capacity by more than 1000 percent and positioning it to be one of the largest licenced producers in Canada.

Mr Gedeon said the scale of the Lucky Lake facility "gives us scope for a massive expansion of our Canadian operations where demand for pharmaceutical grade medical cannabis continues to outstrip supply".

MMJ was unchanged at 24.5 cents.

IDT AUSTRALIA

IDT says it has a manufacturing and supply agreement with the Oakville, Ontario-based Wellspring Pharma Services to assist in the manufacture of generic drugs.
IDT said that Wellspring would assist with products “that require manufacturing processes or scale not currently available at [its] Boronia facilities”.
The company said the first product was pindolol, a cardiac drug with an addressable US market of $US10 million, which had low levels of competition and high margins.
IDT said that placing the products in a second facility “doubles the resources being applied to the re-commercialization of IDT’s proprietary generics range and accelerates progress towards revenues and profitability from our own range of products”.
The company said that the Wellspring products were expected to be available for sale in the US in late 2016.
IDT was up one cent or 3.4 percent to 30.5 cents.

REVA MEDICAL

Reva says its board has elected Brian Dovey as chairman, effective immediately, replacing Robert Stockman who will continue as a non-executive director.
Reva said that Mr Dovey had been a director of the company for about 15 years and has served on its compensation and audit committees.
The company said that Mr Dovey was a partner of life sciences venture capital firm Domain Associates LLC and he joined the board in 2001 when Domain first invested in Reva.
Reva said that Mr Dovey had been a director of more than 35 private and public companies and has been chairman of five companies.
The company said that prior to Domain, Mr Dovey was with Rorer Group,now part of Sanofi-Aventis and before that was president of medical products company Survival Technology.
Reva said that Mr Dovey held a Bachelor of Arts from Colgate University and a Masters of Business Administration from the Harvard Business School.
Reva was unchanged at $1.12.